DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
Telephone: (612) 334-4100
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September 23, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 33

Michael J. LeClair
President
Susie-Q Fish Company, Inc.
1810 East Street
Two Rivers, Wisconsin 54241

Dear Mr. LeClair:

On May 27-30, 2003, we inspected your seafood processing facility located at 1810 East Street, Two Rivers, WI. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operates in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your smoked salmon is adulterated in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links on FDA's home page at *www.fda.gov*.

During our inspection, the investigator provided you with a copy of the form FDA-483, Inspectional Observations, which lists his evaluation of your firm's performance regarding various aspects of the HACCP requirements. Upon further review of the documentation provided to the inspector during the inspection, we find the following deviations:

- You must have and implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed an affirmative step of obtaining a written

guarantee for salmon manufactured by [redacted] that was not adequate in that a copy of the foreign processor's HACCP plan is not maintained by your firm. For your convenience, you may refer to other affirmative step options listed in 21 CFR 123.12(a)(2)(ii) that may better meet your practices. You, as an importer/manufacturer, must be aware of the hazards associated with the products you import and assure that those hazards are addressed in the HACCP plans you obtain as your affirmative steps.

- You must have a HACCP plan, that at a minimum, lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for smoked salmon, smoked whitefish, and smoked chubs, lists a monitoring frequency at the "Refrigeration" critical control point that is not adequate to control pathogen growth and toxin formation. Specifically, your HACCP plan lists a monitoring frequency as "Once-a-day recorded, check continually while working." The *FDA Fish & Fishery Products Hazards & Controls Guidance, Third Edition*, recommends continuous monitoring of cooked ready-to-eat products during refrigeration through the use of a digital time/temperature data logger, or a recorder thermometer, or a high temperature alarm with 24-hour monitoring.

  In addition, your firm's HACCP plan lists an inadequate monitoring frequency at the "Cooling of Smokefish after being pulled-out of the Smokehouse" critical control point as "[redacted] or before, After it was removed from Smokehouse [redacted] or before, After it was pulled from Smokehouse." The *FDA Fish & Fishery Products Hazards & Controls Guidance, Third Edition*, recommends that the continuous monitoring of the initial cooling of the cooked ready-to-eat products be performed by "the use of a dial of digital thermometer and visual check on time of cooling, or a digital time/temperature data logger, or use appropriate instrument and/or visual observations as necessary to measure the critical aspects of the process that affect the rate of cooling, as established by a cooling rate study."

  For additional information regarding recommended control strategies for pathogen growth and toxin formation, please refer to the *FDA Fish and Fishery Products Hazards and Controls Guidance, Third Edition*, Chapter 12 (Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse), found at *www.cfsan.fda.gov/~comm/haccp4.html*.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, failure to correct these violations may result in your product being detained when it is offered for import.

Please respond in writing within 15 working days from receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a copy of your revised HACCP plan reflecting the changes you made along with five days of monitoring records, a copy of your foreign supplier's HACCP plan, and other useful information that will assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct these deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practices regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the attention of Compliance Director David R. Yost at the address in the letterhead.

Sincerely,

W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District